Columvi

Saudi Arabia · access guide

Columvi for relapsed or refractory DLBCL from Saudi Arabia: 2026 pathway via Saudi haematology and CRS/ICANS-capable infusion centres

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

Saudi Arabia runs the deepest adult haematology network in the Gulf. King Faisal Specialist Hospital and Research Centre Riyadh and Jeddah are the long-established reference programmes for relapsed or refractory diffuse large B-cell lymphoma, with extensive experience in autologous stem cell transplant, CAR-T cell therapy (Yescarta, Kymriah, Breyanzi), and now CD20 by CD3 bispecific antibody therapy. King Abdulaziz Medical City under the National Guard Health Affairs, King Fahad Medical City, and the King Faisal Jeddah programme have built parallel haematology and cellular therapy capacity over the last decade. Columvi (glofitamab-gxbm, Genentech / Roche) is the IV CD20 by CD3 T-cell engaging bispecific antibody, given as a fixed-duration 12-cycle course with step-up dosing in week 1 to limit cytokine release syndrome. For a Saudi-resident adult with r/r DLBCL after two or more lines of therapy, or who is being considered for second-line treatment in combination with gemcitabine and oxaliplatin (GemOx) under the July 2025 STARGLO-based label expansion, the operational question is where the step-up dosing happens, which infusion centre has the CRS and ICANS monitoring capability for early cycles, and how the 12-cycle course is funded and supplied.

This page explains the 2026 pathway for a Saudi-resident patient: SFDA registration status, eligibility at the prescribing haematologist clinic, infusion centre selection for the step-up phase, the obinutuzumab pre-treatment requirement one week before first dose, what CRS and ICANS preparedness means in practical infusion-centre terms, the realistic out-of-pocket exposure band in SAR, and how the fixed 12-cycle finish-line shapes the family's planning horizon.

Why Columvi, and why now

Columvi is glofitamab-gxbm, a humanized IgG1 bispecific antibody that binds CD20 on B-cells with one arm and CD3 on T-cells with the other arm, bringing the patient's own T-cells into direct contact with the lymphoma. The FDA approved Columvi in June 2023 under accelerated approval for r/r DLBCL after two or more lines of systemic therapy. In July 2025 the FDA converted that to full approval and expanded the label to include second-line r/r DLBCL in combination with gemcitabine and oxaliplatin (GemOx) based on the STARGLO trial, which showed an overall survival benefit over the standard second-line GemOx-rituximab regimen.

The fixed-duration design is what distinguishes Columvi operationally from indefinite biologic therapy. The treatment is 12 cycles and then it stops. Patients who respond and complete the course are off therapy after roughly 8 to 9 months, with no maintenance phase. For families who have lived through indefinite chemotherapy cycles or who are weighing CAR-T cell therapy (Yescarta, Kymriah, Breyanzi), the off-the-shelf nature of Columvi matters: there is no apheresis collection, no manufacturing wait, and no single one-shot infusion that has to work. Columvi is given as a series of scheduled infusions across 8 to 9 months. The trade-off versus CAR-T is that CAR-T is one infusion and Columvi is twelve; the advantage versus CAR-T is no apheresis, no manufacturing delay, and lower cost.

Reserve Meds does not promote one CD20 bispecific or one CAR-T over another. The page describes the Columvi pathway because Columvi is the drug the patient has asked about.

What Columvi is, in plain language

Columvi is an intravenous infusion given at a hospital with intensive monitoring capacity for the first cycles. The schedule uses step-up dosing across week 1: 2.5 mg on day 1, 10 mg on day 8, and 30 mg on day 15. From cycle 2 onwards the dose is 30 mg every 21 days. The total course is 12 cycles. One week before the first Columvi dose, the patient receives a single 1000 mg infusion of obinutuzumab to deplete circulating CD20 B-cells and reduce the cytokine release syndrome risk of the first Columvi dose.

The infusion centre requirement is central. The step-up dosing phase (week 1) and the cycle 2 dose require infusion centre capacity for CRS and ICANS monitoring: trained staff who can recognise the early signs of cytokine release syndrome (fever, hypotension, hypoxia) and immune effector cell-associated neurotoxicity syndrome (confusion, language disturbance, seizure), tocilizumab and corticosteroids immediately available, ICU escalation pathway, and overnight or 24-hour monitoring availability during early cycles. By cycle 3 onwards, the CRS risk drops sharply and outpatient infusion is generally appropriate for stable patients.

Eligibility at a Saudi haematologist clinic

For Saudi-resident adults, the prescribing haematologist applies the FDA criteria with local infusion-centre adaptation:

1. Confirmed r/r DLBCL not otherwise specified, or large B-cell lymphoma arising from follicular lymphoma, after two or more lines of systemic therapy. Or candidate for second-line treatment in combination with GemOx under the STARGLO 2025 label. 2. Adult (18+). 3. Performance status compatible with intensive monitoring during step-up (ECOG 0 to 2 typically). 4. Adequate organ function: bone marrow, hepatic, renal. 5. No active central nervous system lymphoma. CNS lymphoma is a contraindication. 6. Hepatitis B and HIV screening; HBV reactivation prophylaxis if positive serology. 7. CRS and ICANS preparedness review: the infusion centre confirms tocilizumab availability, ICU escalation pathway, trained staff, and 24-hour monitoring capacity for early cycles. 8. Obinutuzumab pre-treatment one week before first Columvi dose. 9. Hospital with intensive monitoring capacity for early cycles selected before starting.

The Saudi patient should arrive with the most recent oncology documentation: lymph node biopsy with DLBCL pathology confirmation including CD20 status, prior line of therapy documentation (typically R-CHOP first line and a salvage regimen as second line), most recent PET-CT, CNS imaging if there is clinical concern, HBV / HIV serology, and the insurance preauthorisation paperwork that the prescribing office initiates.

The Saudi prescribing and supply picture

Columvi SFDA registration status is verified at intake. Where in-country registration is complete, in-country pharmacy dispensing applies; where the indication-specific label has not yet caught up with the FDA label expansion, a named-patient European-import or US-import pathway covers the case. The pathway is:

1. **Prescribing haematologist**: a board-certified haematologist at KFSHRC Riyadh, KFSHRC Jeddah, King Abdulaziz Medical City NGHA Riyadh or Jeddah, King Fahad Medical City, or an equivalent tertiary haematology programme. The DLBCL bispecific conversation does not happen at general medical oncology; it happens at the lymphoma-experienced adult haematology service. 2. **Infusion centre selection**: KFSHRC Riyadh adult haematology is the primary reference with the deepest CAR-T and bispecific experience in the Gulf. KFSHRC Jeddah, KAMC NGHA Riyadh and Jeddah, and KFMC Riyadh have parallel capacity. The step-up dosing week and cycle 2 dose require the patient to be at the selected infusion centre. From cycle 3 onwards, outpatient infusion at the same centre is appropriate. 3. **Obinutuzumab pre-treatment supply**: arranged through the same infusion centre one week before the first Columvi dose. Most Gulf tertiary haematology services already stock obinutuzumab for CLL and follicular lymphoma indications. 4. **Insurance preauthorisation**: CCHI commercial insurers and the major Saudi commercial covers (Bupa Arabia, Tawuniya, MedGulf, others) handle r/r DLBCL bispecific therapy on a case-by-case basis with documented prior lines, pathology confirmation, and infusion-centre selection. Public-sector Saudi national coverage at KFSHRC, KAMC NGHA, KFMC handles eligible Saudi nationals through the institutional channel. `[VERIFY: current Saudi SFDA registration status per indication at intake.]` 5. **Ongoing monitoring**: haematology follow-up at every cycle; PET-CT response assessment typically at cycle 3 and end of treatment; CRS and ICANS symptom monitoring particularly during early cycles.

Cost band

US list price for Columvi is in the range of USD 250,000 to 380,000 across the full 12-cycle course, with the first cycle (step-up dosing week) being the highest-cost cycle. At 2026 indicative cross rates, the SAR-equivalent total-course cost band is approximately SAR 940,000 to 1,425,000 at list price across the 12 cycles. Insurance preauthorisation reduces out-of-pocket exposure substantially for covered patients; cash-pay exposure depends on the dispensing infusion centre and the obinutuzumab pre-treatment cost layered on top of the Columvi course.

What to expect on Columvi

Week 1 is the step-up dosing phase. The patient receives 2.5 mg on day 1, 10 mg on day 8, and 30 mg on day 15, with intensive CRS and ICANS monitoring at the infusion centre. CRS, when it occurs, typically appears within 6 to 24 hours of the day 1 or day 8 dose and presents as fever, sometimes with hypotension or hypoxia. The infusion centre manages CRS with tocilizumab and corticosteroids per standard protocol. ICANS, when it occurs, typically appears within the first one to two cycles and presents as confusion, language disturbance, or in rare cases seizure. The infusion centre manages ICANS with corticosteroids and supportive care.

By cycle 3 onwards, the CRS and ICANS risk drops sharply and outpatient infusion is generally appropriate. The patient continues 30 mg every 21 days through cycle 12 and then stops. PET-CT response assessment at cycle 3 and at end of treatment guides clinical decisions. The fixed 12-cycle finish line is the operational anchor of Columvi: the patient knows where the treatment ends.

When Columvi is the wrong drug

For a Saudi patient with active CNS lymphoma (a contraindication; CNS-directed therapy is the priority), with a fragile clinical state where the patient cannot tolerate the CRS risk of step-up dosing, with very early-line disease where R-CHOP first line or standard salvage chemotherapy has not yet been tried, or where the prescribing haematologist judges CAR-T cell therapy (Yescarta, Kymriah, Breyanzi) to be a better fit because of curative-intent framing and the patient is fit for apheresis and the manufacturing wait, the pathway shifts. Reserve Meds does not promote one CD20 bispecific or one CAR-T over another. If the conversation with the treating haematologist points toward CAR-T, Epkinly (epcoritamab subcutaneous CD20 by CD3 bispecific), or continued chemo-immunotherapy, the operational pathway shifts accordingly.

What Reserve Meds does on this case

We are a US-based concierge coordinator. We are not the prescriber and not the dispensing infusion centre. On a Saudi Columvi case we build the documentation pack with the treating haematologist office at KFSHRC Riyadh, KFSHRC Jeddah, KAMC NGHA, or KFMC, confirm SFDA registration status and the appropriate dispensing pathway, run the insurance preauthorisation conversation alongside the clinical preauthorisation conversation, coordinate the obinutuzumab pre-treatment one week before first dose, confirm the CRS and ICANS preparedness at the selected infusion centre, and stay with the case through the 12-cycle course with handoff to the local haematologist for end-of-treatment response assessment. Clinical decisions remain with your treating haematologist and the infusion centre.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.
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